

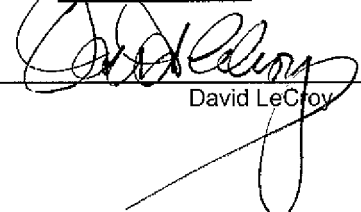
PATENT APPLICATION
Attorney Docket No. 3049.SPD

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: DIHEL, Deborah L. *et al.*
SERIAL NO.: 10/783 078 **GROUP ART UNIT:** 1616
FILED: 20 February 2004 **EXAMINER:** GEORGE, Konata M.
ENTITLED: DISSOLVABLE FILM COMPRISING AN ACTIVE INGREDIENT AND
METHOD OF MANUFACTURE

CERTIFICATE of TRANSMISSION UNDER 37 C.F.R. § 1.8

I hereby certify that this correspondence is being transmitted to the United States Patent and Trademark Office via the USPTO web-based EFS on 15 February 2008.



David LeCroy

Mail Stop Appeal Brief - Patents
Commissioner for Patents
Post Office Box 1450
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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Dear Sir:

In compliance with the requirements of 37 C.F.R. § 41.37(c), Appellants respectfully submit their brief in furtherance of the Notice of Appeal, which was transmitted to the United States Patent and Trademark Office on 13 February 2008.

I. REAL PARTY IN INTEREST

National Starch and Chemical Investment Holding Corporation is the owner of the entire right, title and interest in and to the invention described in this patent application by virtue of an Assignment from the inventors, which Assignment was recorded in the United States Patent and Trademark Office on 20 February 2004 at Reel 015012, Frame 0770.

II. RELATED APPEALS AND INTERFERENCES

With respect to all other prior and/or pending appeals, interferences or judicial proceedings that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal, there are no such appeals or interferences known to Appellant, Appellant's legal representative or assignee.

III. STATUS OF CLAIMS

Claims 1-13 are pending in this application. Claims 1-13 stand rejected. No claims have been allowed.

The claims on appeal are claims 1-13, which are set forth in the attached Claims Appendix.

IV. STATUS OF AMENDMENTS

All claims stand as amended in Applicant's Reply of 27 August 2007, and as entered in the Examiner's Action of 14 November 2007.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The following summary of the subject matter defined in each of the independent claims involved in the Appeal is offered to enable the Board to more quickly determine where in the application enabling embodiments of the claimed subject matter are described. However, because other embodiments may fall within the scope of the claims, this summary should not be construed as limiting of the claims hereafter discussed.

Claim 1 is the only pending independent claim, with remaining claims 2-13 depending directly from claim 1. For ease of reference, claim 1 is as follows –

1. A method of making a dissolvable film comprising a substance, the method comprising mixing film forming ingredients together to form a mixture, coating the mixture onto a suitable substrate to form a film, applying a substance to the film, and drying the film to a moisture content of about 10 weight % or less moisture.

From the above independent claim it is seen that the present invention is generally directed towards a method or process for preparing dissolvable films containing substances such as flavorings or other actives that would otherwise be lost in the preparation of the film (p. 2, lines 4-7). The process involves mixing together water-soluble film forming ingredients in an aqueous solution thereby forming an aqueous film pre-mix, coating a substrate with that mixture thereby forming a film, applying a substance onto the film and then drying the film (p. 3, lines 16-22). By preparing dissolvable films in this manner, substances such as flavors or active ingredients can be added to the film composition without losing their efficacy. For example, volatile flavorings can be encapsulated in water-soluble encapsulating material and then added to the film (p. 2, lines 15-25). Adding the encapsulated volatile to the film pre-mix would result in the dissolution of the capsule and release of the volatile, which is not desirable. Even if the active substance is encapsulated in an oil-based encapsulant, processing conditions in the pre-mix can cause the oil-soluble capsules to melt (p. 2, lines 1-3). The present invention provides a method for enabling one to form dissolvable containing such substances without risking loss of the efficacy of those substances (p. 2, lines 21-23 and p. 3, lines 1-4).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection presented for in this Appeal are:

- (a) Whether claims 1-13 should be rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 7,025,983 to Leung *et al.* ("Leung").

VII. APPELLANT'S ARGUMENTS

- A. REJECTION UNDER 35 U.S.C. § 103(a) AS BEING UNPATENTABLE OVER U.S. PATENT NO. 7,025,983 TO LEUNG

Claims 1-13 stand rejected as being unpatentable over Leung. For the following reasons, Applicants respectfully request reconsideration of the Examiner's final rejection of claims 1-13 under 35 U.S.C. § 103(a).

1. The Standard for Obviousness

The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966), stated that three factual inquiries underpin any determination of obviousness –

Under [35 U.S.C.] § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

The Supreme Court reaffirmed and relied upon the *Graham* three pronged test in its consideration and determination of obviousness in the fact situation presented in *KSR Int'l v. Teleflex Inc.*, 550 US ___, 82 USPQ 2d 1385, 1391 (Apr. 30, 2007). The Court stated –

While the sequence of these [Graham] questions might be reordered in any case, the factors continue to define the inquiry that controls. If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103.

KSR, 550 US ___, 82 USPQ 2d at 1391. The Court further stated –

To facilitate review, this analysis should be made explicit. *See In re Kahn*, 441 F.3d 977, 988 [78 USPQ2d 1329] (CA Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness”).

2. The Scope and Content of the Prior Art

Leung teaches fast dissolving orally consumable films. The edible films include antimicrobially effective amounts of the essential oils thymol, methyl salicylate, eucalyptol and menthol (Abstract). According to a preferred method of producing essential oil-containing films, (1) water-soluble ingredients are dissolved in water to form an aqueous mixture, (2) the film forming ingredients are mixed together in powdered form to form a powdered mixture, (3) the

powdered mixture is added to the aqueous mixture to form a gel; (4) stirring the gel at room temperature for some length of time; (5) forming an oil mixture of cooling agent and essential oils; (6) adding other essential oils and surfactants to the oil mixture; (7) adding the oil mixture to the gel and mixing until uniform; (8) deaerating the mixture to remove air bubbles; (9) casting the mixture onto a substrate; and (10) drying the cast mixture to form a film (col. 11, lines 45-61). (col. 3, lines 17-18; col. 5, lines 25-61; claim 1).

As such, Leung teaches making its films by mixing all its ingredients together and then forming a film. In contrast, method claim 1 and its dependent claims 2-5 of the present invention teach making the film and then adding a substance onto the film. By doing so, volatile and/or active substances that would lose their efficacy when prepared according to the teachings of Leung are able to be delivered without such loss in a dissolvable film. Nowhere does Leung teach this step of adding a substance after the film is made, or provide any motivation to do so. Accordingly, Leung does not render obvious claims 1-5. Further, with specific reference to dependent method claims 2 and 3, it is admitted by the Examiner that Leung makes absolutely no

Regarding composition claims 6-13, the Examiner alleges that it would have been obvious to one skilled in the art at the time the invention was made to encapsulate a volatile substance for the purpose of reducing evaporation of the substance. As admitted by the Examiner, Leung makes absolutely no reference to the use of encapsulated substances, particularly for the delivery of volatile substances such as its flavoring agents and essential oils. Leung states that its film former (pullulan) used in making its films "entraps" the oral care agents in the oral cavity to provide extended efficacy (col. 3, lines 6-9; *see also*, col. 4, lines 15-19). Leung also states that the preferred method for essential oil containing films is to do so without heating the films as "heating results in undesirable losses of volatile ingredients to evaporation, which also affects the germ killing activity" of the film (col. 11, line 62 – col. 12, line 1). Leung also suggests mixing the oil in the aqueous film pre-mix by a two-step process in order to minimize loss of flavor (col. 12, 1-2). However, Leung is silent with respect to ensuring that the efficacy of its flavorings, oils and actives are maintained through the manufacture and storage of its films. Accordingly, Leung provides no motivation to one skilled in the art to look to the use of encapsulated substances as Leung alleges that its invention is able to deliver volatile substances. Further, the present invention states that merely encapsulating the volatile substance

may not be sufficient as processing conditions can affect the encapsulant. One skilled in the art therefore would also not learn or be motivated from Leung to prepare films wherein the volatile substance is added to the film, rather than added in the mixture of ingredients used in making the film

3. The Claims of the Present Invention are not Anticipated or Obvious

As noted in the 'Summary of the Invention' above, the present invention is directed towards dissolvable films and their method of manufacture that enables substances such as volatiles and active ingredients to be added to the film without their losing their efficacy. Nowhere does Leung preparing a film premix, casting that premix onto a substrate and then adding such substances. Instead, Leung teaches adding volatiles such as flavoring, essential oils and pharmaceutical agents to its film premix and then casting its premix to form its films.

Applicants take notice of the Examiner's remarks in his 8 February 2008 Advisory Action. According to the Examiner, "[a]pplying the substance onto the film would have been obvious for a few reasons". First, the Examiner states that by adding the substance after the film is formed, the integrity of the substance can be maintained. However, in the 'Background of the Invention' of the present Specification, it is noted that there is a need in the art for method of preparing films that can be used for the delivery of substances such as volatiles. Accordingly, Applicants assert that the Examiner has done nothing other than made use of impermissible hindsight.

In support of Applicants' position, reference is made to the sole reference cited by the Examiner in support of his obviousness rejection. Leung, as noted above, utilizes a variety of substances in forming its films, including volatile oils and flavors and pharmaceutical actives. Leung believes that the pullulan used in making its films "entraps" the volatile oils in the oral cavity to provide extended efficacy (col. 3, lines 6-9; *see also*, col. 4, lines 15-19). However, Leung states in its Examples that the actual amount of each ingredient in its finished dried film depends upon the amount of moisture removed during drying (col. 16, lines 41-43). Further, Leung notes that the films formed according to Examples 7 and 9 with the microcrystalline cellulose AVICEL® are more acceptable in regards to handling and processing, but have reduced efficacy compared to films prepared without AVICEL® (Example 8). Accordingly, Leung seeks

to improve efficacy by modifying the ingredients used in forming the films. Nowhere does Leung suggest adding volatiles and/or actives AFTER forming the film; therefore, from the teachings of Leung one skilled in the art would only consider seeking other film forming ingredients in order to improve the efficacy in delivery of its actives.

With respect to the Examiner's second remark that by adding the substance after the film is made to ensure that the appropriate amount is added to achieve the desired results, Applicants respectfully refer the Board to Example 3 of the present application, which illustrates that the Examiner's remark is not correct. There, the efficacy of encapsulated flavors was compared to non-encapsulated flavors wherein both were added after preparation of films. From Example 3 it is seen that films containing the encapsulated flavors performed with better results. Further, as noted above with respect to Leung, one skilled in the art is instructed to prepare the films without heating and to add the oil to the film pre-mix in a two-step process in order to "ensure that the appropriate amount of substance is [included in] the film to achieve the desired results of the substance".

Accordingly, with respect to claims 2, 3 and 6-13, it is admitted by the Examiner that Leung makes no reference to the use of encapsulated ingredients. Further, it is a fact that Leung provides no teaching or suggestion to add a substance to the film after the film is formed. Accordingly, the Examiner has done nothing other than to use impermissible hindsight in support of his rejection of the presently claimed invention.

For all the foregoing reasons, the Examiner has failed to establish a *prima facie* case of obvious under 35 U.S.C. § 103(a) of any of claims 1-13. Accordingly, the rejection under 35 U.S.C. § 103(a) should be reversed.

VIII. CONCLUSION

For the reasons mentioned above, Appellant's dissolvable film composition is not made obvious in view of Leung as Leung does not teach dissolvable films having disposed on at least one surface thereof an encapsulated substance, or methods for producing films by adding there onto a substance after formation of the film on a substrate.

For all of the foregoing reasons, it is respectfully submitted that the final rejection of all claims is untenable and should not be sustained. Allowance of the claims is believed to be in order, and such allowance is respectfully requested.

Respectfully submitted,

Dated: 15 February 2008

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A handwritten signature in dark ink, appearing to read 'David P. LeCroy', written over a horizontal line.

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CLAIMS APPENDIX

Claims of U.S. Application No. 10/783 078 on Appeal

1. A method of making a dissolvable film comprising a substance, the method comprising mixing film forming ingredients together to form a mixture, coating the mixture onto a suitable substrate to form a film, applying a substance to the film, and drying the film to a moisture content of about 10 weight % or less moisture.
2. The method of claim 1 wherein the substance is an encapsulated substance.
3. The method of claim 2 comprising a water soluble encapsulant.
4. The method of claim 1 wherein the formed film having the substance applied thereon is air-dried.
5. The method of claim 1 wherein the formed film having the substance applied thereon is dried under warm air.
6. A dissolvable film having disposed on at least one surface thereof an encapsulated substance.
7. The film of claim 6 the encapsulated substance is a volatile substance.
8. The film of claim 6 wherein the encapsulated substance is a flavor.
9. The film of claim 6 comprising pullulan and/or starch.
10. The film of claim 9 comprising a modified starch.
11. The film of claim 10 wherein the modified starch is hydroxyalkylated starch or succinated starch.

12. A method of preserving the flavor of an active to be delivered by a film, the method comprising encapsulating the active in a water soluble encapsulant and placing the encapsulated active on the surface of the film.
13. The method of claim 12 wherein the encapsulated active is placed on the film after film forming stage, but prior to drying stage.

EVIDENCE APPENDIX

No evidence has been submitted pursuant to 37 C.F.R. §§ 1.130, 1.131 or 1.132, nor is there any other evidence entered by the Examiner and relied upon by appellant in this appeal. Therefore, no copies of such evidence are to be had for the purpose of this Appendix.

RELATED PROCEEDINGS APPENDIX

As noted in Section II of the current Appeal Brief, no decisions have been rendered by a court or the Board in any proceeding related to, directly affected by or have a bearing on the Board's decision in the pending appeal. Therefore, no copies of such decisions are to be had for the purpose of this Appendix.